

**REMARKS**

The Final Office Action mailed June 3, 2009 has been received and reviewed. In the Final Office Action, the Examiner has:

(1) objected to claim 22 as being of improper dependent form for failing to further limit the subject matter of a previous claim;

(2) objected to claims 11 and 18 as being substantially duplicative of claim 8; to claims 29 and 30 as being substantially duplicative of claim 26; and to claim 35 as being substantially duplicative of claim 32;

(3) rejected claims 1, 2, 4-11, 18-23, and 25-30 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, for allegedly comprising new matter;

(4) rejected claims 20-31 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, for allegedly comprising new matter;

(5) rejected claims 1, 4, 5, 7-11, 18-20, 22, 23, 25-36, 38, 40, and 42 under 35 U.S.C. § 103(a), as allegedly being unpatentable over Zimmer et al.; Bonyhadi et al.; and Grignani et al.;

(6) rejected claims 1, 2, 4, 5, 7-11, 18-23, 25-36, 38, and 40-42 under 35 U.S.C. § 103(a), as allegedly being unpatentable over Zimmer et al.; Bonyhadi et al.; Gaines et al.; and Grignani et al. as applied to claims 1, 4, 5, 7-11, 18-20, 22, 23, 25-36, 38, 40, and 42 above, and further in view of Arruffo et al. (U.S. Patent No. 5,540,926) as further evidenced by Wohlgemuth et al. (PCT International Publication No. WO 04/042345);

(7) rejected claims 1, 2, 4, 5-11, 18-23, 25-36, 38, and 40-42 under 35 U.S.C. § 103(a), as allegedly being unpatentable over Zimmer et al.; Bonyhadi et al.; Gaines et al.; and Grignani et al.; and Arruffo et al. as further evidenced by Wohlgemuth et al. as applied to claims 1, 2, 4, 5, 7-11, 18-23, 25-36, 38, and 40-42 above, and further in view of Lawson et al. (U.S. Patent No. 7,052,906); and

(8) rejected claims 1, 2, 4, 5, 7-11, 18-23, and 25-42 under 35 U.S.C. § 103(a), as allegedly being unpatentable over Zimmer et al.; Bonyhadi et al.; Gaines et al.; Grignani et al.; Arruffo et al., as further evidenced by Wohlgemuth et al.; and Lawson et al. as applied to claims

1, 2, 4, 5, 7-11, 18-23, 25-36, 38, and 40-42 above; and further in view of Selden et al. (U.S. Patent No. 6,303,379).

In connection with this response, claims 1, 2, 4-11, 18-23, and 25-42 are hereby cancelled (without prejudice or disclaimer). Claims 3, 12-17 and 24 have previously been cancelled (without prejudice or disclaimer). New claims 43-80 have been added. No new subject matter has been added in connection with the amendments. Upon entry of the above amendments, claims 43-80 remain pending in the present application.

In view of the Request for Continued Examination being filed herewith, and in view of the foregoing amendments and following remarks, reevaluation and reconsideration of the application is requested.

### **Objections**

With respect to item (1), it will simply be noted that claim 22 has hereby been cancelled (without prejudice or disclaimer). Therefore, the objection is moot and should be withdrawn.

### **Indication of Potential Double Patenting**

With respect to item (2), it will simply be noted that claims 8, 11, 18, 26, 29, 30, 32 and 35 have hereby been cancelled (without prejudice or disclaimer). Therefore, the objection is moot and should be withdrawn.

### **35 USC § 112**

With respect to items (3) and (4), it will simply be noted that claims 1, 2, 4-11, and 18-31 have hereby been cancelled (without prejudice or disclaimer). Therefore, the rejections are moot and should be withdrawn.

### **35 U.S.C. 103(a)**

With respect to item (5), it will simply be noted that claims 1, 4, 5, 7-11, 18-20, 22, 23, 25-36, 38, 40, and 42 have hereby been cancelled (without prejudice or disclaimer). Therefore, the 35 U.S.C. § 103(a) rejection is moot and should be withdrawn.

With respect to item (6), it will simply be noted that claims 1, 2, 4, 5, 7-11, 18-23, 25-36, 38, and 40-42 have hereby been cancelled (without prejudice or disclaimer). Therefore, the 35 U.S.C. § 103(a) rejection is moot and should be withdrawn.

With respect to item (7), it will simply be noted that claims 1, 2, 4, 5-11, 18-23, 25-36, 38, and 40-42 have hereby been cancelled (without prejudice or disclaimer). Therefore, the 35 U.S.C. § 103(a) rejection is moot and should be withdrawn.

With respect to item (8), it will simply be noted that claims 1, 2, 4, 5, 7-11, 18-23, and 25-42 have hereby been cancelled (without prejudice or disclaimer). Therefore, the 35 U.S.C. § 103(a) rejection is moot and should be withdrawn.

### **New Claims 43-80**

In connection with the present Amendment and Response, new claims 43-80 have been added to set forth certain novel features of the present invention. Support for these new claims can be found throughout the specification as filed, and specifically, at least in paragraphs 10-16, 40-42, 54, 95-145 and 154-156 of the published application. No new matter has been added.

New independent claim 43 recites, in part, an expression vector for transducing a target cell of a host wherein, when the extracellular domain of the  $\alpha$ -chain of the CD8 is expressed on a surface of the target cell transduced with the expression vector, an immune reaction by the host directed to expression vector associated antigens and the therapeutic molecule of interest is suppressed. None of the prior art references teach or disclose suppressing an immune reaction by a host directed to expression vector associated antigens and a therapeutic molecule of interest. Accordingly, Applicants submit that new independent claim 43 cannot be rendered obvious by Zimmer et al. in view of Bonyhadi et al., Grignani et al., Gaines et al., Aruffo et al., Lawson et al., Selden et al. or Wohlgemuth et al.

New independent claim 56 recites, in part, an expression vector for transducing a target cell of a host wherein, when the extracellular domain of the  $\alpha$ -chain of the CD8 is expressed on a surface of the target cell transduced with the expression vector, persistence of expression of the therapeutic molecule of interest is achieved by suppressing an immune reaction by the host directed to vector associated antigens and the therapeutic molecule of interest. None of the prior

art references teach or disclose persistence of expression of a therapeutic molecule of interest by suppressing an immune reaction by a host directed to expression vector associated antigens and the therapeutic molecule of interest. Accordingly, Applicants submit that new independent claim 56 cannot be rendered obvious by Zimmer et al. in view of Bonyhadi et al., Grignani et al., Gaines et al., Aruffo et al., Lawson et al., Selden et al. or Wohlgemuth et al.

New independent claim 69 recites, in part, an expression vector for transducing a target cell of a host wherein, when the extracellular domain of the  $\alpha$ -chain of the CD8 is expressed on a surface of the target cell transduced with the expression vector, persistence of expression of the therapeutic molecule of interest is achieved by suppressing responding CD4<sup>+</sup> T cells and CD8<sup>+</sup> T cells of the host such that an immune reaction by the host directed to expression vector associated antigens and the therapeutic molecule of interest is inhibited. None of the prior art references teach or disclose persistence of expression of a therapeutic molecule of interest by suppressing responding CD4<sup>+</sup> T cells and CD8<sup>+</sup> T cells of a host such that an immune reaction by the host directed to expression vector associated antigens and the therapeutic molecule of interest is inhibited. Accordingly, Applicants submit that new independent claim 69 cannot be rendered obvious by Zimmer et al. in view of Bonyhadi et al., Grignani et al., Gaines et al., Aruffo et al., Lawson et al., Selden et al. or Wohlgemuth et al.

## CONCLUSION

Based on the changes and remarks provided above, Applicants submit that the pending claims are clear, concise, and are neither anticipated nor rendered obvious by the cited references. Accordingly, Applicants submit that pending claims 43-80 are in condition for allowance. Withdrawal of the pending rejections, and early and favorable reconsideration are respectfully solicited. In the event that a telephone conversation would further prosecute and/or expedite allowance, the Examiner is invited to contact the undersigned at (617) 310-6000.

Applicants request a five (5) month extension of time in connection with the filing of this RCE and Response, and authorizes the Examiner to charge an amount of \$1,580.00 (\$1,175.00 for 5 month extension of time, \$405.00 for RCE filing fee) to Deposit Account No. 50-2678, Reference 108674-010401, to cover the requisite fee. Applicants do not believe that any additional fees are required in connection with this Response. However, should any fees be required for timely consideration of the present application, Applicants hereby petition for same and request that the fees required for timely consideration of this application be charged to Deposit Account No. 50-2678, Reference 108674-010401.

Respectfully submitted,

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